

REMARKS

In view of the following remarks, the Examiner is requested to allow Claims 1-11 and 17-20, the only claims pending and under examination in this application.

FORMAL MATTERS

Claims 1-11 and 17-20 have been examined and rejected.

Claims 12-14, and 21-38 have been previously withdrawn.

Claim 1 has been amended for clarification.

Accordingly, no new matter has been added.

As no new matter has been added by the above amendments, entry thereof by the Examiner is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 4, 7, 9, 10, 17, 18 and 20 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai (US Publication No. 2005/0065574) in view of Verrier et al. (5,437,285).

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics v. Viacell et al.*, 2007 U.S. App. LEXIS 16245 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007))); and see *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. 2007) ("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art," (citing KSR Int'l Co. at 1741)); and see *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) ("[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,'" (citing *In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

The rejected claims are directed to a method of treating a female subject known to suffer from a fertility condition. The method includes modulating at least a portion of the autonomic nervous system of the female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. The method further includes determining the sympathetic activity/parasympathetic activity ratio prior to the modulation and performing the modulation of a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio.

The Office asserts that Rezai discloses modulating a portion of the autonomic nervous system of a female subject known to suffer from a fertility condition, because Rezai includes the conditions of 'infertility' and 'painful menses' in the list of "hypothalamic-related conditions".

Rezai discloses affecting a "hypothalamic-related condition" by electrically or chemically stimulating the hypothalamus (see Abstract). Rezai discloses a list of over 55 conditions allegedly related to the hypothalamus. These conditions include an extremely diverse range of conditions including infertility, baldness, narcolepsy, lethargy, dwarfism, and facial blushing (page 3, Table II). However, Rezai does not provide any further teaching or suggestion as to how the method is to be applied specifically to each condition.

The Office acknowledges that Rezai does not disclose determining a ratio of sympathetic activity to parasympathetic activity. The Office therefore relies upon Verrier, et al., which allegedly teaches an ANS sensing system wherein the ratio of sympathetic activity to parasympathetic activity is determined to sense the vulnerability of the organ innervated by the ANS.

Verrier et al. disclose a method directed to individuals with potentially fatal heart conditions. In the "Abstract", Verrier et al. state that the method is "for predicting susceptibility to sudden cardiac death simultaneously assessing cardiac electrical stability and autonomic influence" (Abstract, emphasis added). In the "Summary of the Invention", Verrier et al. state that the method disclosed is for diagnosing "cardiac vulnerability to ventricular fibrillation" (and col. 6, lines 4-5). In the "Detailed Description of the Preferred Embodiment", Verrier et al. state the method is for "individuals at risk for sudden cardiac death" (col. 9, lines 50-51, emphasis added). In regards to sympathetic activity/parasympathetic activity ratio, Verrier et al. disclose that it is "indicative of sympathetic activity or vagal withdrawal" (col. 7, lines 28-29).

For these reasons, it is very clear that Verrier et al. only disclose determining the sympathetic activity/parasympathetic activity ratio of an individual with a potentially fatal heart condition.

Because Rezai is silent as to activity ratio and Verrier is specifically limited to heart conditions, there is no indication or suggestion in the references that determining sympathetic activity/parasympathetic activity ratio of an individual would have any relevance to treating a female for a fertility condition.

As such, the combination of Rezai and Verrier et al. do not teach or suggest all of the claimed limitations.

In view of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Rezai and Verrier fails to teach or suggest all the claimed limitations, namely modulating the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition. Consequently, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 1, 4, 7, 9, 10, 17, 18 and 20 be withdrawn.

Claims 2 and 3 have been rejected under 35 U.S.C. § 102(e) as anticipated by Rezai, or in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Rezai in view of Bothe Loncar et al. (US Publication No. 2002/0188336).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claims 2 and 3 depend from Claim 1. As set forth above, elements of the rejected claims are directed to a method of treating a female subject known to suffer from a fertility condition. The method includes determining a sympathetic activity/parasympathetic activity ratio and modulating at least a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat the female subject for the fertility condition.

As described above, Rezai is deficient in that it does not disclose determining a ratio of sympathetic activity to parasympathetic activity, much less modulating at least a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio. Accordingly, the Applicants contend that Rezai does not anticipate the Applicants' invention because Rezai fails to teach every element of the rejected claims. Therefore, the Applicants respectfully request that the rejection of Claims 2 and 3 under 35 U.S.C. § 102(e) be withdrawn.

Similarly, Claims 2 and 3 are not obvious over Rezai in view of Bothe Loncar. As discussed above, Rezai does not disclose determining a ratio of sympathetic activity to parasympathetic activity, much less modulating at least a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio. Therefore, Rezai does not teach or suggest all the claim limitations. As Bothe Loncar is cited solely for its alleged disclosure of modulating the autonomic nervous system during the luteal phase of the menstrual cycle, it fails to remedy the deficiencies of Rezai.

Therefore, a *prima facie* case of obviousness has not been established because the combination of Rezai and Bothe Loncar fails to teach or suggest all the claimed limitations, namely modulating a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. The Applicants' therefore respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 2 and 3 over Rezai in view of Bothe Loncar be withdrawn.

Claims 5, 6 and 11 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Whitehurst et al. (USPN 6,832,114).

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics v. Viacell et al.*, 2007 U.S. App. LEXIS 16245 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007))); and see *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. 2007)

("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,'" (citing KSR Int'l Co. at 1741)); and see Dystar Textilfarben GmbH v. C.H. Patrick Co., 464 F.3d 1356, 1360 (Fed. Cir. 2006) ("[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,'" (citing In re Fulton, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

Claims 5, 6 and 11 depend from Claim 1. As set forth above, Claim 1 is directed to a method of modulating at least a portion of the autonomic nervous system of a female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat the female subject for a fertility condition.

As described above, Rezai discloses affecting a "hypothalamic-related condition" by electrically or chemically stimulating the hypothalamus (see Abstract), and discloses a list of over 55 conditions allegedly related to the hypothalamus (page 9, Table II). However, Rezai does not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject and modulating the ANS of the subject based on the determined sympathetic activity/parasympathetic activity ratio.

The addition of Whitehurst et al. does not cure the deficiency of Rezai. Whitehurst et al. disclose modulating a patient's pancreatic endocrine secretion by electrical stimulation to treat diabetes. However, Whitehurst et al. do not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject and modulating at least a portion of the autonomic nervous system of the subject to increase the sympathetic activity/parasympathetic activity ratio of the subject.

Since neither Rezai nor Whitehurst et al. disclose this claim element, both references, either alone or combined, do not teach or suggest all the claim limitations of Claims 5, 6 and 11.

In view of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Rezai with Whitehurst fails to teach or suggest all the claimed limitations, namely modulating at least a portion of the autonomic nervous system of a female subject to increase the sympathetic activity/parasympathetic activity ratio in manner effective to treat a female subject for a fertility condition. Consequently, the Applicants respectfully request that the the 35 U.S.C. § 103(a) rejection of Claims 5, 6, and 11 be withdrawn.

Claim 8 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Mann et al. (US Publication No. 2002/0055761).

Claim 8 depends from Claim 1. As set forth above, Rezai fails to teach or suggest modulating a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition. As Mann is cited solely for its alleged disclosure of stimulating a pelvic nerve (i.e., to treat incontinence, urgency, frequency, or pelvic pain), it fails to remedy the deficiencies of Rezai. Mann does not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject and modulating the ANS of the subject based on the determined sympathetic activity/parasympathetic activity ratio.

Since neither Rezai nor Mann et al. disclose this claim element, both references, either alone or combined, do not teach or suggest all the claim limitations of Claim 8.

Therefore, a *prima facie* case of obviousness has not been established because the combination of Rezai with Mann fails to teach or suggest all the claimed limitations,

namely modulating at least a portion of the autonomic nervous system of a female subject to increase the sympathetic activity/parasympathetic activity ratio in manner effective to treat a female subject for a fertility condition. The Applicants therefore respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 8 be withdrawn.

Claim 19 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rezai in view of Khan et al. (US Publication No. 2002/0064501).

Claim 19 depends from Claim 1. As set forth above, elements of the rejected claims include a method of modulating at least a portion of the autonomic nervous system of a female subject to increase the sympathetic activity/parasympathetic activity ratio so as to treat the female subject for a fertility condition. As described above, Rezai fails to teach or suggest modulating a portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio so as to treat a female subject for a fertility condition.

The addition of Khan does not remedy the deficiency of Rezai. Khan discloses using an immunoregulator to treat an immune-mediated disorder, including "chronic inflammatory disease, such as diabetes type I or II, rheumatic disease, Sjogrens syndrome, multiple sclerosis, transplantation-related immune responses such as graft-versus-host-disease, post-transfusion thrombocytopenia, chronic transplant rejection, pre-eclampsia, atherosclerosis, asthma, allergy and chronic auto-immune disease, and acute inflammatory disease" (paragraph [0028]). However, Khan does not disclose determining the sympathetic activity/parasympathetic activity ratio of a subject and modulating the ANS of the subject based on the determined sympathetic activity/parasympathetic activity ratio.

Therefore, Khan does not remedy the deficiencies of Rezai. Consequently, a *prima facie* case of obviousness has not been established because the combination of Rezai and Khan fails to teach or suggest all the claimed limitations, namely modulating

at least a portion of the autonomic nervous system of a female subject to increase the sympathetic activity/parasympathetic activity ratio in manner effective to treat a female subject for a fertility condition. Consequently, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 19 be withdrawn.


CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.


The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number PALO-004.

Respectfully submitted,
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